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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,074	03/02/2004	John J. Dunn	BSA 02-16	7913

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EXAMINER	
SHIBUYA, MARK LANCE	
ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 08/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/791,074	DUNN ET AL.	
	Examiner	Art Unit	
	Mark L. Shibuya	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4/10/2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-94* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-94* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-94 are pending.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-22, 50-55, 58-63, drawn to methods for analyzing organismic complexity, classifiable in class 435, subclass 6.

II. Claims 23-47, drawn to a method for analyzing the complexity of a single stranded nucleic acid in a sample, classifiable in class 435, subclass 6.

III. Claims 50-55, drawn to a method for analyzing the variety of members of specific phyla or families of organisms, classifiable in class 435, subclass 6.

IV. Claims 56, 57, drawn to a method for identifying methylated CpG island-associated genome signature tags, classifiable in class 435, subclass 6.

V. Claims 64-66, drawn to a method for determining a visualizable change in organismic complexity of a sample from one sampling time to the next, classifiable in class 435, subclass 6.

VI. Claims 67-86, drawn to a method for generating a listing of genome signature tags from fragmented genomic DNA, classifiable in class 435, subclass 6.

VII. Claims 48, 49, 94, drawn to a composition of matter comprising a collection of substantially duplex DNA amplification adapters having a degenerate, ligatable overhang, classifiable in class 435, subclass DIG 37.

VIII. Claims 87-90, drawn to a primer pair comprising a first primer and a second primer, classifiable in class 536, subclass 24.33.

Claim 91 link(s) inventions I-VI. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 91.

Claim 92 link(s) inventions I-VI. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 92.

Claim 93 link(s) inventions I-VI. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 93.

Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

3. The Inventions of Groups I-VI are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the

inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the uses intended for the different methods, i.e., analyzing organismic complexity, analyzing the complexity of a single stranded nucleic acid in a sample, analyzing the variety of members of specific phyla or families or organisms, identifying methylated CpG island-associated genome signature tags, determining a visualizable change in organismic complexity of a sample from one sampling time to the next, and generating a listing of genome signature tags from fragmented genomic DNA, have materially different design, mode of operation, function and effect.

The Inventions of Groups VII and VIII are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, one of the primers of the primer pair of Group VIII does not hybridizes to the amplification adapter of Group VII, and therefore has a materially different nucleotide sequence from the adapters of Group VII.

The Inventions of Groups VII and VIII and the Inventions of Groups I-VI are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as

claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the amplification adapters and primer pairs (products) may be used as hybridization probes, which is a materially different process of using.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a

matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

> In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**
>
> Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Election of Species

5. This application contains claims directed to the following patentably distinct species: A method comprising a single specific binding pair, or a first and second specific binding pair. The species are independent or distinct because the methods comprising more than one specific binding pair is a materially different design and mode of operation from the method comprising just one specific binding pair.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 23 are generic.

6. This application contains claims directed to the following patentably distinct species: A specific anchoring enzyme. The species are independent or distinct because the different anchoring enzymes have different molecular sequences, recognize different substrates, and so have materially different modes of action and effect.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 7, 8, 23, 35, 36, 48, 50, 58, 63, 64, 67, 78 are generic.

7. This application contains claims directed to the following patentably distinct species: A type IIS restriction enzyme. The species are independent or distinct because the different type IIS restriction enzymes have different molecular sequences, recognize different substrates, and so have materially different modes of action and effect.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 23, 48, 50, 64, 67, 78 are generic.

8. This application contains claims directed to the following patentably distinct species: A specific binding pair. The species are independent or distinct because the

different binding pairs have different sequences, and so have materially different modes of operation, function and effect.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 11, 23, 38 are generic.

9. This application contains claims directed to the following patentably distinct species: A solid support. The species are independent or distinct because the different supports have different molecular structures that result in different bonds that have materially different design, mode of operation, function and effect.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 12, 23, 39 are generic.

10. This application contains claims directed to the following patentably distinct species: A second specific binding pair that is (a) identical or (b) different to the specific binding pair of claim 1. The species are independent or distinct because the second binding pairs have materially different design, function and effect.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 3 are generic.

11. This application contains claims directed to the following patentably distinct species: Sequencing performed by (a) pyrosequencing or capillary gel electrophoresis. The species are independent or distinct because the different sequencing procedures have materially different modes of operation.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 4, 16, 17, 23, 42 are generic.

12. This application contains claims directed to the following patentably distinct species: A biological specimen. The species are independent or distinct because the different biological specimens have different sources that result in materially different design and modes of operation.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 18-22, 23, 43-47 are generic.

13. This application contains claims directed to the following patentably distinct species: An ultimate single-stranded nucleic acid, specified as to RNA or DNA, and origin of the single-stranded nucleic acid. The species are independent or distinct because the different nucleic acids have materially different modes of operation and because the different the different origins have materially different chromosomal organization and complexity.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 23 is generic.

14. This application contains claims directed to the following patentably distinct species: A location of the SP-GSTs to the gene of focus. The species are independent or distinct because the different locations on the chromosome relative to the gene of focus result in materially different design and modes of operation.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 50-52 are generic.

15. This application contains claims directed to the following patentably distinct species: A gene of focus. The species are independent or distinct because different genes have different nucleotide sequences and locations on the chromosome, which result in materially different modes of operation.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 50, 53-55 are generic.

16. This application contains claims directed to the following patentably distinct species: Methods with (a) one fragmenting enzyme or (b) with a first and a second

fragmenting enzyme. The species are independent or distinct because the different methods comprising different numbers of primer pairs have materially different modes of operation.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 58 are generic.

17. This application contains claims directed to the following patentably distinct species: A species of first fragmenting and a species of a second fragmenting enzyme. The species are independent or distinct because each of the fragmenting enzymes fragment the nucleic in a characteristic manner and so have materially different modes of operation, function and effect.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 58-61 are generic.

18. This application contains claims directed to the following patentably distinct species: An adapter associated type II restriction enzyme recognition sequence. The species are independent or distinct because the different recognition sequences have different nucleotide sequences, and so have materially different modes of operation and effect.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 67 is generic.

19. This application contains claims directed to the following patentably distinct species: A method of fragmenting sample DNA. The species are independent or distinct because the different methods of fragmenting have materially different modes of operation.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 67, 78 are generic.

20. This application contains claims directed to the following patentably distinct species: A method comprising an amplification adapter comprising ligatable 3' overhangs that are (a) 4-fold, (b) 8-fold, or (c) 16-fold degenerate sequences. The species are independent or distinct because the different fold degenerate sequences have result in materially different modes of operation and effects.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 9, 23, 37, 67, 76, 78, 86 are generic.

21. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

22. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of

record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

23. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Shibuya whose telephone number is (571) 272-0806. The examiner can normally be reached on M-F, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mark L. Shibuya
Examiner
Art Unit 1639